

# Salivary cortisol in children with asthma and/or rhinitis: effect of topical steroids and correlation with symptoms and lungfunction

Published: 06-09-2010

Last updated: 04-05-2024

Evaluate the effect of topical steroids on salivary cortisol levels, and assess the correlation between salivary cortisol levels, symptoms of asthma, and lungfunction in children with asthma and/or rhinitis

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Adrenal gland disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON34524

### Source

ToetsingOnline

### Brief title

Effect of topical steroids on salivary cortisol level in children

### Condition

- Adrenal gland disorders

### Synonym

adrenal function, cortisol level

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Leeuwarden

**Source(s) of monetary or material Support:** wetenschapsfonds Auletius Instituut (Wetenschapsfonds Medisch Centrum leeuwarden) en eigen Stichting Pediatrie Leeuwarden

## Intervention

**Keyword:** children, salivary cortisol, topical steroids

## Outcome measures

### Primary outcome

difference in salivary cortisol level before and during or after treatment with topical steroids

### Secondary outcome

correlation of salivary cortisol, symptoms of asthma, and lungfunction

## Study description

### Background summary

Collection of saliva is a well established noninvasive way to assess cortisol levels in children. We have recently demonstrated that salivary cortisol levels are significantly lower in children using inhaled and/or intranasal steroids compared to a control group. It is unknown if the reduced salivary cortisol levels are due to the chronic inflammatory disease or to the use of topical steroids.

To the best of our knowledge, salivary cortisol levels have not been determined in individual children before, during and after treatment with topical steroids. Furthermore, it is not known if there is any correlation between cortisol levels and symptoms or lungfunction.

In the present study we want to evaluate intraindividual salivary cortisol levels before, during and after treatment with topical steroids. This way we are able to determine whether topical steroids induce an additional suppression of salivary cortisol levels, and if these levels increase after discontinuation of the steroids. We also aim to study the correlation between salivary cortisol levels, symptoms of asthma, and lungfunction.

### Study objective

Evaluate the effect of topical steroids on salivary cortisol levels, and assess

the correlation between salivary cortisol levels, symptoms of asthma, and lungfunction in children with asthma and/or rhinitis

## Study design

All eligible children who visit our ambulatory pediatric asthma clinic in the period september 2010- september 2011, will be asked to participate. Standard diagnostic procedures will be performed (lungfunction and allergy test). The following data will be recorded: height, weight, body mass index, Tanner state, type of inhalation device, allergies. For newly diagnosed patients, duration of symptoms and dose of prescribed topical steroids. For patients in whom the topical steroids are discontinued, the dose of topical steroids used in the last 3 months are recorded.

In addition, the asthma symptom score will be recorded on the day the saliva is collected by using the validated asthma control test for children.

## Study burden and risks

Collection of saliva by chewing on a cottonwool swab is considered childfriendly and with minimal burden. We expect no risk for the participants

## Contacts

### Public

Medisch Centrum Leeuwarden

Henri Dunantweg 2  
8934 AD  
NL

### Scientific

Medisch Centrum Leeuwarden

Henri Dunantweg 2  
8934 AD  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

### Inclusion criteria

children 6-18 years

newly referred children who are diagnosed with asthma and/or rhinitis and who are not already using topical steroids

children with stable asthma and/or rhinitis in whom topical steroids can be tapered down to zero according to international guidelines

### Exclusion criteria

informed consent is not obtained

if a child is unwilling to participate during the study

a chronic medical condition other than asthma and/or rhinitis

use of oral steroids in the past 3 months

use of concurrent medication which may potentially affect steroid metabolism

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 03-03-2011

Enrollment: 40

Type:

Actual

## Ethics review

Approved WMO

Date:

06-09-2010

Application type:

First submission

Review commission:

RTPO, Regionale Toetsingscie Patientgebonden Onderzoek  
(Leeuwarden)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register**

CCMO

**ID**

NL33148.099.10